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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,329	12/21/2001	Jean-Louis Touraine	109993	6765

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OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,329	TOURAINE ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *25-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/21/02, 4/29/01*. 6/4102, 8/5102
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152).
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

This office action is in response to an amendment filed 2/24/04.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-24) in the amendment filed 2/24/04 is acknowledged. The traversal is on the ground(s) that the subject matter of all of claims 1-38 is sufficiently related that there is no search burden in examining all of the claims, in view of MPEP 803. This is not found persuasive as MPEP 803 teaches "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant." Group I and II comprise divergent subject matter for which a search for art pertaining to each group is not coextensive. A search for art pertaining to nucleotide fragments encoding CD4, IgG3 and elements required for replicating (Group I) is not coextensive with a search for art pertaining to methods for treating infectious disease (Group II). This prima facie showing has not been rebutted by a showing or evidence to the contrary by the applicants.

The requirement is still deemed proper and is therefore made FINAL. Therefore, an examination of claims 1-24 follows. Claims 25-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Information Disclosure Statement

IDSs filed 12/21/01, 4/29/02, 6/4/02, 8/5/02 have been identified and the documents considered. The signed and initialed PTO Form 1449s has been mailed with this action.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, a statement did not accompany the submission of the substitute Paper Copy and Computer Readable Form of the Sequence listing, filed 4/29/01, that the substitute sequence listing and the Computer Readable Form are the same and do not constitute New Matter.

Claim Objections

Claims 1-24 are objected to in as much as they are drawn to non-elected subject matter as they read on sequences that have not been elected, and should be redrafted without said subject matter.

Claim 1 is objected to because of the following informalities: Claim 1, line 3, "an" should be "a", line 3,"an" should be "a". Claim 1, line 8 recites "peptide" in the singular where it should be plural. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and by dependency claims 2-24 are vague and indefinite in that the metes and bounds of a "human soluble CD4" are unclear. It is unclear if the CD4 must be the human encoded form of CD4 or must be **soluble** in humans.

Claim 1 and by dependency claims 2-24 are vague and indefinite in that the metes and bounds of "an nucleotide sequence (b) comprising at least nucleotide sequences" are unclear. It is unclear how **an** nucleotide sequence can encode nucleotide **sequences**. Furthermore, use of the word "an" implies that the sequence can be any dinucleotide nucleotide from a mammalian sequence.

Claim 1 and by dependency claims 2-24 are vague and indefinite in that the metes and bounds of sequences encoding "immunoglobulin IgG3" are unclear. It is unclear if the sequences are meant to encode a specific antibody that is IgG3 or any antibody that is a member of the IgG3 subclass of antibodies.

Claims 1-5 and 13 and by dependency claims 6-12 and 14-24 are vague and indefinite in that the metes and bounds of "nucleic elements" are unclear. It is not clear what the meaning of "nucleic elements" is. "Nucleic elements" can refer to *cis*-acting responsive elements for binding of proteins or coding sequences encoding proteins that function for replication.

Claims 1-5 and by dependency claims 6-24 are vague and indefinite in that the metes and bounds of "under control" are unclear. It is unclear to what the nucleic elements are under control.

Claim 9 is vague and indefinite in that the metes and bounds of "further comprises nucleotide sequences encoding the heavy chain and the light chain of 2F5 monoclonal antibody" are unclear. The composition of claim 1 comprises nucleotide sequence (b) which comprises the nucleotide sequences encoding IgG3 heavy and light chain directed against the peptide encoded by SEQ ID NO: 2. It is disclosed in the specification that 2F5 is directed against SEQ ID NO 2. It is unclear if it is intended that two copies of the same coding sequence be included in the composition.

Claim 12 is vague and indefinite in that the metes and bounds of "murine Moloney leukemia retrovirus type" are unclear. It is unclear how much of the vector must be retroviral to be a "retrovirus type" or if specific retroviral components make the vector "retrovirus type". If specific retroviral components makeup the "retrovirus type",

what components are required? It would be remedial to amend the claim to read on the murine Moloney leukemia vector i.e. "is a Murine Moloney leukemia vector".

Claims 19-20 are vague and indefinite in that the metes and bounds of "tissue of genetically modified cells" are unclear. Tissues are comprised of cells and intracellular substances that together perform a function. Therefore, it is unclear what a "tissue **of** genetically modified cells" is.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10-18 and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Leroy (US 2002/0107869 A1; see entire document).

Leroy et al teach encapsulated implants comprised of genetically modified cells comprising an exogenous nucleotide sequence coding for all or part of an antibody (see e.g. abstract and paragraph 0069 and 0089). The implant comprises any set of genetically modified cells, preferably fibroblasts, that have incorporated the exogenous nucleic acids i.e. antibody coding sequences (see e.g. paragraph 0013). The protein expressed by the exogenous sequence is capable of forming a multimer (see e.g. paragraph 0062). In a preferred embodiment of the invention, the cells are used to treat HIV-1 infection with the encoded antibody (see e.g. paragraph 0020). The vector in

Figure 2 discloses a vector with an expression cassette comprised of a nucleotide sequence comprising 2F5 heavy chain (HC) and light chain (LC) separated by an IRES sequence under the control of the PGK promoter. 2F5 is an IgG3 molecule (see e.g. paragraph 0132). In another embodiment, HIV-1 infection is treated with genetically modified cells comprising sequences encoding an antibody modified with an immunopotentiating protein (see e.g. paragraph 0020 and 0025). The specification teaches that an immunopotentiating protein can be the extracellular domain of CD4 (sCD4) and a portion of 2F5 antibody (see e.g. paragraph 0026 and 0129 and figure 8). Figure 8 discloses a fusion construct comprised of expression cassettes of sCD4 and 2F5 under control of the PGK promoter or murine phosphoglycerate kinase promoter (see e.g. paragraph 0031). 2F5 and the sCD4-2F5 constructs are expressed as separate expression cassettes in vectors (see e.g. figure 2 and 8). Embodied vectors include viral vectors specifically a murine Moloney leukemia retrovirus (see e.g. paragraph 0035). 2F5 monoclonal antibody is directed against SEQ ID NO:2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

March 26, 2004

GERRY LEFFERS
PRIMARY EXAMINER